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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,260

12/01/2005

Gordon Blunn

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1471

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7590

08/18/2009

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EXAMINER

STROUD, JONATHAN R

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

08/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/544,260	<b>Applicant(s)</b> BLUNN ET AL.	
	<b>Examiner</b> JONATHAN R. STROUD	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 1-44 and 55-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of the election in the reply filed on 06/03/2009 is acknowledged. The traversal is on the ground(s) that the restriction was improper for at least three reasons. This is not found persuasive for a number of reasons, including other considerations. For instance, a reamer need not be used to enact a reaming step; for instance, reaming can be done with scissors, a file, two protrusions, or a number of devices. Further, in order to select a prosthetic femoral head having a certain dimension, one need not have a plurality of femoral heads ready, or in fact any femoral heads; it would be possible to take that information and select a desired prosthetic femoral head, and then shape that head. Furthermore, a reamer could be used to do any number of mechanical activities, from widening holes in wood without measuring a body characteristic first to being used as a blunt force trauma instrument.

The requirement is still deemed proper and is therefore made FINAL. Claims 45-54 will now be examined on the merits.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ries 5,782,928, further in view of McGuire 2005/0202371 further in view of Zaleski 2003/0101076.

Ries 5,782,928 teaches a method of preparing a subject's body for implantation including determining at least one body characteristic, reaming the hip joint's acetabulum, selecting a prosthetic device for implantation corresponding to the at least one body characteristic, and implanting the selected prosthetic device into the space.

Further, since the shapes of the acetabular cups selected are dependent upon the previously determined body characteristics, so to then does it naturally flow that the femoral heads would be similarly selected, either as a mating pair to those acetabular cups, or independently based on the information provided.

Ries does not teach leaving a space that specifically allows for 0.5-2 MPa of hydrostatic pressure to accumulate. However, it is likely that this amount of hydrostatic pressure will accumulate at some point in the surgical procedure and/or at some time following.

Furthermore, McGuire teaches the desirability and means to create cartilage through body compression and hydrostatic pressures of greater than 0.015MPa, and further, tested in the range of 500-700 kPa (or 0.5-0.7kPa) and higher, pars. [0197-0200], in order to promote bone and cartilage growth.

Ries in view of McGuire does not explicitly state the step of measuring the patient's body mass or body weight in order to select an appropriate prosthesis.

However, all surgeons know of the importance of patient information in surgical decisions, and generally, patient information is collected prior to surgeries in order to assist the surgeon in decision-making – such as is disclosed in Zaleski 2003/0101076, BMI, patient weight, and other various factors are normally collected and on hand for any surgeon making medical decisions. Therefore, it would be obvious to one of ordinary skill in the art to measure a patient's body weight and use that information to inform the choice of prosthetic device.

Re claims 46 and 47, as stated above, McGuire discloses the desirability of any and all hydrostatic pressures above 0.0015 MPA that do not then damage the tissue, and discloses values of 0.5MPa and up. Since it is well known in the art that a hydrostatic pressure of specifically 2Mpa would not damage the tissue, it would be a matter of routine experimentation to one of ordinary skill in the art to determine this variable.

Re claims 48-52, in the current configuration, a spacer element or membrane of cartilage will form *in situ* and be resorbable.

Re claim 53, the surface of the prosthetic will deform as taught by McGuire, para. [0009].

Re claim 54, as stated above, but also as taught by Ries, other body characteristics such as the diameter of the reamed socket, the patient's vitals and the dimensions of their body are determined or can be determined.

It would have been obvious to one of ordinary skill in the art to modify Ries in view of McGuire, in order to create cartilage through body compression and increase

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the likelihood of cartilage regeneration, and further to modify those in view of Zaleski and the general knowledge of the art, in order to utilize the inherent information provided most surgeons in order to make better informed decisions of the choice of prosthetic to be implanted.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/  
Examiner, Art Unit 3774

/William H. Matthews/  
Primary Examiner, Art Unit 3774